ClinicalTrials.gov: Record Keeping Tips

Protocol Registration

Verify the study registration

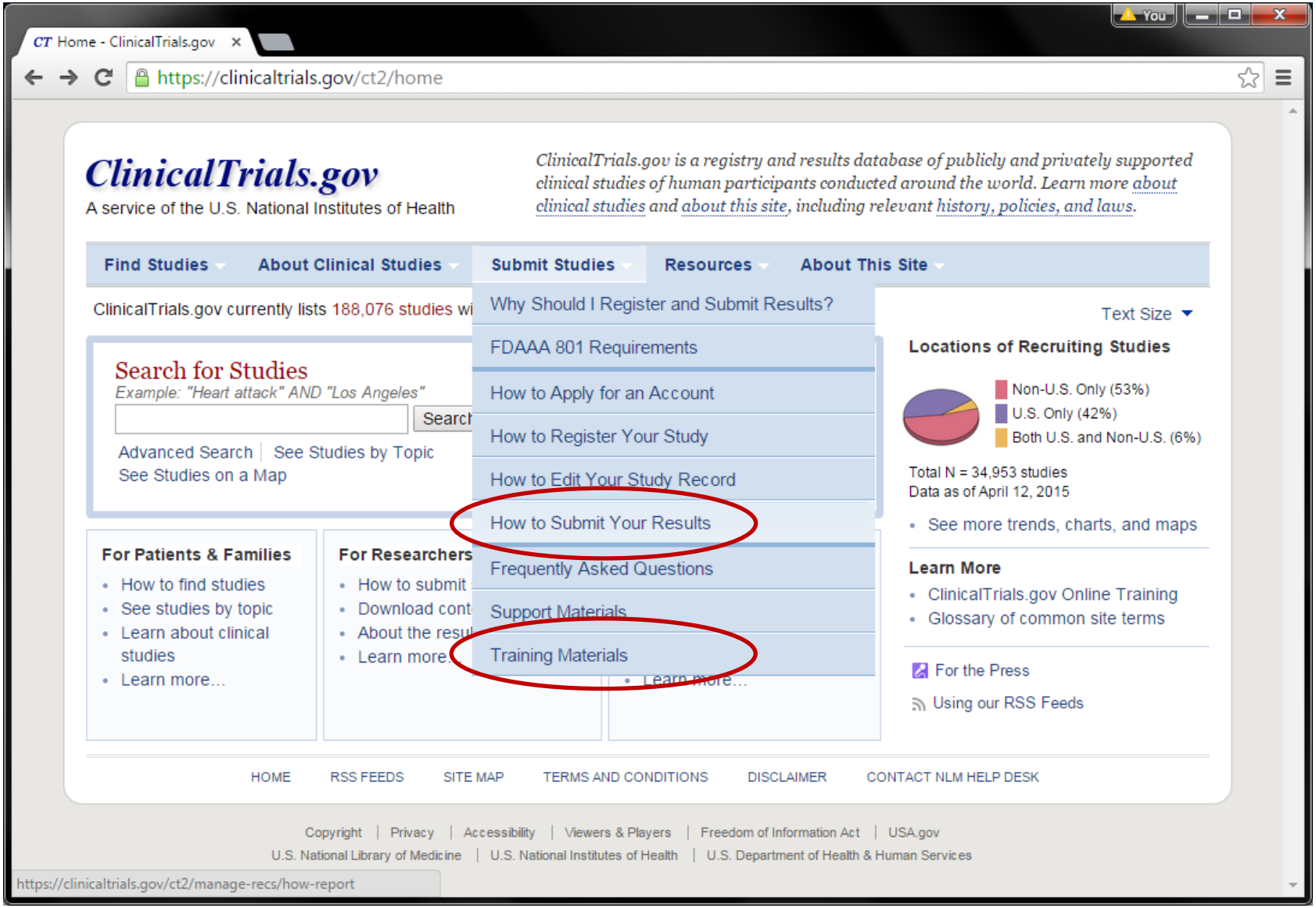
- Before the record is released to ClinicalTrials.gov, or as soon as it is posted on the public site, verify that all of the information in the record is correct
  - Study Type, Study Design and Phase
  - Outcome Measures
  - Study and Primary Completion Dates
  - Arms and Interventions
  - Eligibility
- As the study proceeds, update the information in the record as necessary, particularly when there are Protocol amendments

Submitting Results

Before Entering Results

- Verify that the Protocol information is correct. Update and Release the record before beginning Results if necessary.
- Review some of our help documentation to help you prepare:
  - ClinicalTrials.gov → Submit Studies → How to Submit your Results
    - Results Data Preparation Checklists
    - Simple Results Templates
    - Results Data Element Definitions
  - ClinicalTrials.gov → Submit Studies → Training Materials
    - Example Studies for Results Data Entry
- Do a search on ClinicalTrials.gov for a similar study design

ClinialTrials.gov: Submit Studies



Results Data Preparation Checklists

ClinicalTrials.gov

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Outcome Measure Data Preparation Checklist

Overview: A tabular summary of outcome measure results by comparison group. You must report tables for each pre-specified primary and secondary outcome and any appropriate statistical analyses. The outcomes that were pre-specified in the Protocol Section of the record will be available to use and edit during results data entry. You may also include other pre-specified and *post hoc* outcomes. Use this checklist with the Outcome Measure Simple Results Template[Δ] and Results Data Element Definitions.

	Information to have available for each Outcome Measure	Term
☐	• Label the measure as Primary, Secondary, Other Pre-specified, or Post hoc.	*[Δ]Outcome Measure Type

☐	• Title—Describe specifically what was measured and will be reported as data
	  ○ For example, "Change from baseline in systolic blood pressure at 6 months" specifically describes what was measured and how the outcome data will be reported; "Principle Vital Signs" does not.
	• Description—Any elaboration needed to understand the measure and the reported data. Information should be written for a public audience (i.e., not specialists in your field, but general readers of the medical literature).
	  ○ For example, a description of how the measure was taken, relevant definitions (e.g., explain "response"), any methods of assessment, and/or calculations that were performed to summarize the data
	  ○ If the measure was based on a scale, explain any numerical categories or provide the range and direction of possible scores (0=no pain; 10=worst possible pain) to allow a reader to properly interpret any reported values.
		*[Δ]Outcome Measure Title
		[Δ]Outcome Measure Description

☐	• The time point(s) or duration over which a participant was assessed for the measure, and for which data are being reported ○ For a time-to-event measure—A definition of the stopping rule and the longest duration over which a participant was observed (e.g., from randomization until death, up to 3 years)	*[Δ]Outcome Measure Time Frame
☐	• The number of separate groups for which summary data will be provided • Tip: Generally equal to the number of intervention strategies or groups compared	Arm/Groups

☐	• For each group:
	  ○ Title—A descriptive label for the group (header for table column). Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1").
	  ○ Description—A detailed explanation of the participants included in the group and the interventions received. This may include a description of how groups of participants were recombined for analysis purposes.
		*[Δ]Arm/Group Title
		[Δ]Arm/Group Description

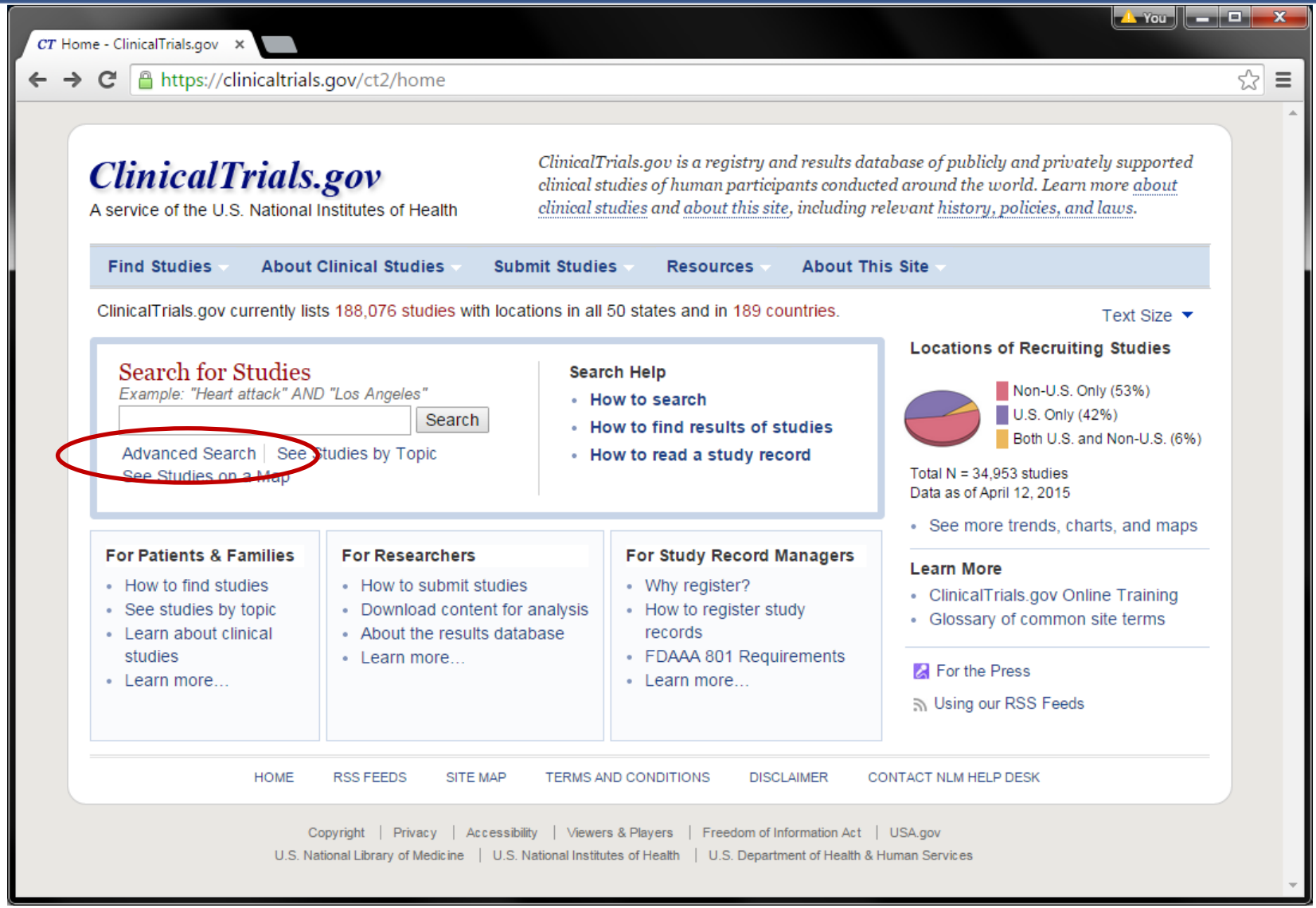
☐	• Number of participants, in each group, from whom data were collected and summarized. ○ If the unit of analysis is not participants, also provide the name of the unit (e.g., eyes, lesions) and the number of units [Type/Number Units Analyzed].	*[Δ]Number of Participants Analyzed

Simple Results Templates

* Outcome Measure Type	*(Circle One)* Primary	Secondary	Other Pre-specified	Post-Hoc	Safety Issue?	*(Circle One)* Yes	No
* Outcome Measure Title							
Outcome Measure Description							
* Outcome Measure Time Frame							

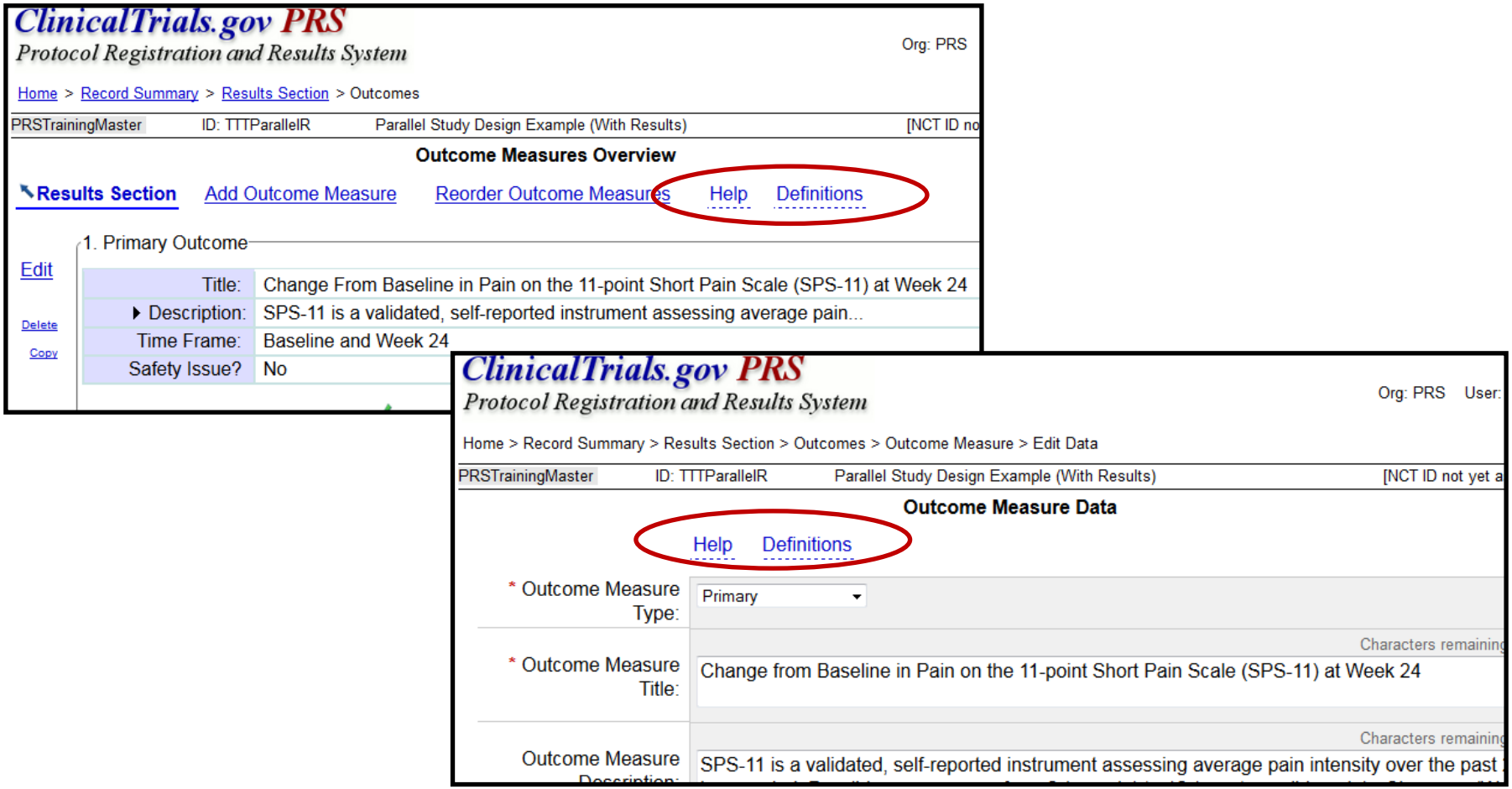
* Arm/Group Title						
Arm/Group Description						
* Number of Participants Analyzed						
Analysis Population Description						
* Measure Type	* Measure of Dispersion/Precision					
(Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	*(Circle One)* Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error 95% Confidence Interval 90% Confidence Interval Geometric Coefficient of Variation					
[*] Category Title						
[*] Category Title						
* Unit of Measure						

Search for a Results Record with a Similar Study Design



During Entering Results

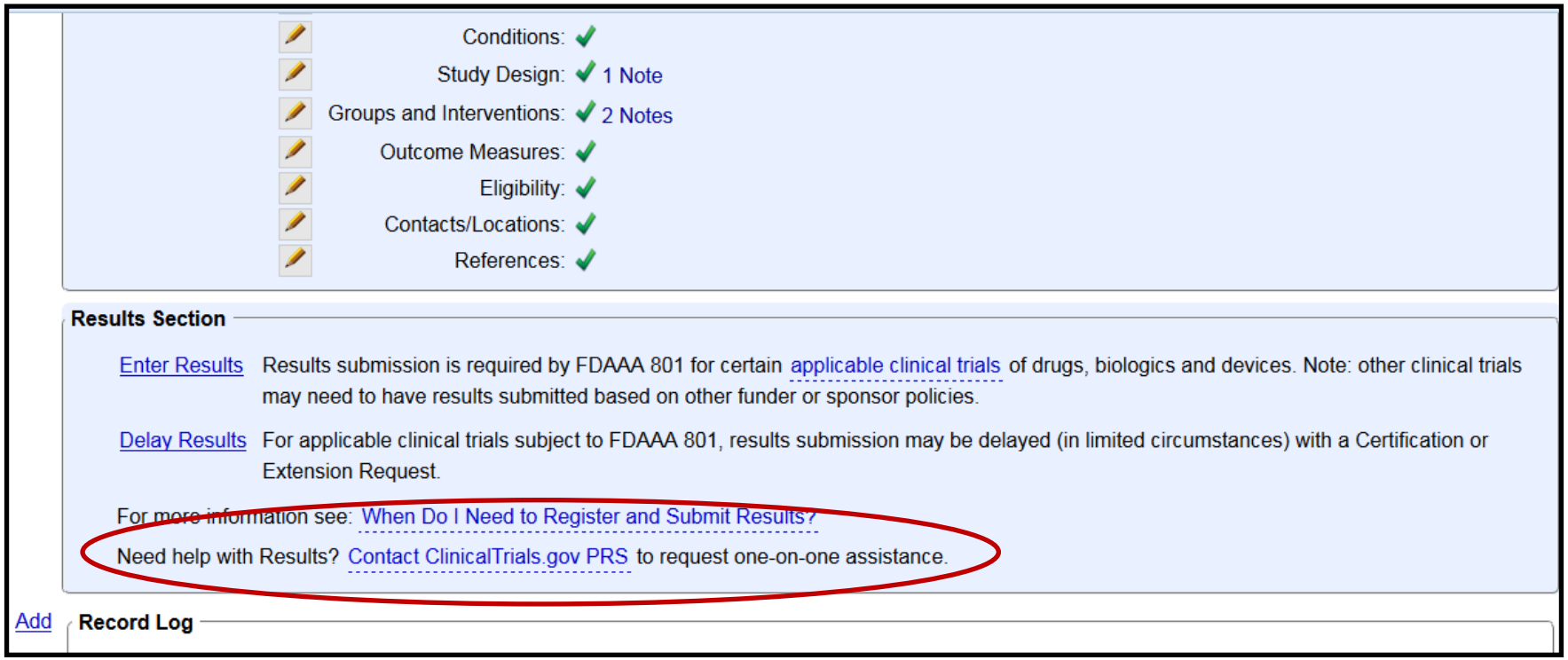
- Use the Help and Definitions links within the PRS



Request 1-on-1 Assistance

ClinicalTrials.gov offers 1-on-1 assistance for investigators throughout the results submission process.

- Contact us using the link at the bottom of the the Record Summary page



OR contact us at ANY time via email: register@clinicaltrials.gov